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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Detroit District
300 River Place
Suite 5900
Detroit, MI 48207
Telephone: 313-393-8100
FAX: 313-393-8139

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
2003-DT-21

August 29, 2003

Mr. Bernardus H. Amting, Owner
Amting Dairy Farm
17451 N Drive North
Marshall, MI 49068

Dear Mr. Amting:

An inspection of your dairy operation located at 17451 N Drive North, Marshall, Michigan 49068 was conducted by a Food and Drug Administration (FDA) Investigator Cathie S. Marshall on June 4-5, 2003. The inspection confirmed that you offered a dairy cow for sale for slaughter for food in violation of Section 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act). A food is adulterated if it bears or contains a new animal drug (or conversion product thereof) that is unsafe within the meaning of section 512 of the Act.

On March 25, 2003, you sold a dairy cow identified with a plastic ear tag no. 780 to [redacted] applied back tag number ST34 XH2712 and sold the animal to [redacted] (doing business as [redacted], where the dairy cow was slaughtered for human food on March 26, 2003. The United States Department of Agriculture, Food Safety Inspection Service (UDSA-FSIS) analyzed tissue samples collected from this animal and identified the presence of 62.54 parts per million (ppm) of gentamicin in the kidney tissue and 1.97 ppm gentamicin in the liver.

According to Title 21 Code of Federal Regulations (CFR) 522.1044 and 529.1044, gentamicin sulfate is not approved for use in bovine species. No tolerance for residues of gentamicin in the edible tissues of bovine species has been established (21 CFR § 556.300).

The presence of gentamicin in the edible tissues of this animal causes the food to be adulterated within the meaning of section 402(a)(2)(C)(ii) of the Act. Gentamicin is not approved for use in dairy cattle; use of gentamicin in dairy cattle is therefore contrary to the approved conditions of

use. Such an extralabel use is permitted only on the lawful order of a licensed veterinarian within the context of a valid veterinarian-client-patient relationship and in conformance with the criteria set forth in 21 CFR Part 530, including that there be no residue which may present a risk to human health. Because your extralabel use of gentamicin resulted in the presence of a drug residue in edible tissue that might present a risk to human health, use of the drug was not in compliance with extralabel use regulations. 21 CFR 530.10, 530.11(c). The drug is therefore unsafe under section 512 of the Act, which renders the food adulterated under section 402(a)(2)(C)(ii) of the Act.

A food is also adulterated under section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions...whereby it may have been rendered injurious to health." As it applied in this case "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions which may allow medicated animals bearing possibly harmful drug residues to enter the food supply.

For example, our investigator noted the following conditions on your farm:

1. You do not maintain an adequate medication/treatment system to identify: the animal treated, date of medication, the drug dosage administered, and the drug pre-slaughter withdrawal time. For example, there were no drug treatment records available for the dairy cow identified with ear tag #780, which was offered for sale and subsequently slaughtered for human food use and found to have violative levels of gentamicin in the kidney and liver tissues.

2. You do not systematically review drug treatments to the animals prior to offering an animal for slaughter for human food. This is to assure that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous drug residues from edible tissues.

3. You lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in their label.

This letter is not intended to be an all-inclusive list of violations. As a producer of dairy cows that are offered for use as human food, you are responsible for assuring that your overall operations and the food you distribute are in compliance with the law.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you caused the adulteration of an animal that was sold and subsequently offered for sale in interstate commerce to a slaughter facility is sufficient to hold you responsible for violations of the Act.

You should take prompt action to correct these violations and to establish procedures to prevent their recurrence.

Failure to promptly correct these violations may result in regulatory sanctions without further notice. These sanctions include, but are not limited to, seizure or injunction. This letter notifies you of our findings and provides you an opportunity to correct the above deficiencies. This letter constitutes official notification under the law.

We note that this is not the first time that illegal residues have been found in your animals. The USDA-FSIS reported finding illegal gentamicin residues in a dairy cow offered for slaughter on September 6, 2000, and two Bob veal calves offered for slaughter on July 31, 2002.

You should notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the date by which the corrections will be completed. Include copies of any available documentation demonstrating that corrections have been made.

Your response should be directed to Ms. Judith Jankowski, Compliance Officer, at the above address.

Sincerely yours,

Joann M. Givens
District Director
Detroit District Office